REMARKS

Applicants kindly thank the Examiner for the opportunity to discuss the issues in this case with her during the telephone interviews on February 13, 2004 and March 3, 2004.

Applicants have submitted a Request for Continued Examination under 37 CFR § 1.114 with this Preliminary Amendment at the suggestion of the Examiner. Claims 1-9, 11-18, 20-38, 40, 41and 43-46 are pending. Claims 10, 19, 39 and 42 have been withdrawn. New claims 47 and 48 have been added. Favorable reconsideration and allowance is respectfully requested.

Election/Restriction:

Applicants respectfully maintain their traversal of the restriction requirement. Based on the discussion during the interview with the Examiner on March 3, 2004, during which the Examiner stated that she would reconsider the restriction requirement based on the amendments to claims 1 and 18, Applicants respectfully request that the Examiner reconsider the restriction requirement. In this Preliminary Amendment, Applicants have reentered claims 17, 37 and 44 for reconsideration.

Claim Objections:

Applicants thank the Examiner for renumbering misnumbered claims 43-45. The renumbered claims 43-46 are reflected in the listing of the claims.

In the Drawings:

The Examiner objected to the drawings under 37 CFR 1.83(a) for failing to show the needle and the cannula as separate elements in FIGS. 1-11. Applicants have amended FIGS. 1, 2 and 5 to show the needle and the cannula as separate elements. FIGS. 3 and 4 show the injector device after the transcutaneous placement of the cannula on the skin of the patient. Thus, FIGS. 3 and 4 do not show the cannula. FIGS. 6-10 have been amended in the previous response, mailed October 14, 2003, to

show the needle and the cannula as separate elements. A copy of the FIGS. 6-10 previously submitted is attached to the Appendix. No new matter has been added.

Applicants respectfully assert that the newly amended FIGS. 1, 2 and 5 and previously amended FIGS 6-10 show the structural details essential for a proper understanding of the disclosed invention.

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings 1-11 under 37 CFR 1.83 (a).

The Examiner objected to the drawings under 37 CFR 1.84 (p)(4) because the character "113" has been used to designate both the infusion tubing set and spring (see FIGS. 6-8). As discussed in the telephone interview on February 13, 2004, Applicants respectfully assert that the element 113 as shown in FIGS. 6 and 7 represents infusion tubing wound up in the lower part of an annular space 115 between the device housing 128 and the plunger 130 as indicated on page 10, line 27. The spring is represented by element 136, shown and described on page 11, lines 17-20, wherein the spring 136 may comprise a number of elongated plastic strips 136.

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings under CFR 1.84 (p)(4) because element 113 refers to the infusion tubing and the element 136 refers to the spring.

The Examiner objected to the drawings under 37 CFR 1.83(a) for failing to show every feature of the invention specified in the claims. Applicants have amended the claims to remove the reference numerals. Applicants therefore assert that the rejection of FIGS. 1-5 and 13-16 for failing to show tubing 113 has been obviated. Claims 10, 19, 39 and 42 directed to a safety retainer have been withdrawn to expedite prosecution.

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings under 37 CFR 1.83(a).

The Examiner objected to the drawings under 37 CFR 1.84(p)(5) because they include the following reference signs not mentioned in the description: 221, 212A, 237, 264 and 232 as shown in FIGS. 13-16.

With respect to the numeral 221, Applicants have amended the specification on page 14, to correct the typographical error on line 16 to correctly state "slot 221" and not

"slot 220". The numeral 220 refers to the tab as shown in FIG. 13 and described on page 14, line 15.

With respect to numeral 212A, Applicants have amended the specification in the paragraph beginning on line 22 to include "insertion needle 212 with forward end 212A". Support for the amendment with respect to 212A can be found in original claim 3.

Applicants have removed reference numeral 237 from FIGS. 14 and 16.

Reference to elements 264 and 232 may be found in the description in the paragraph beginning on page 13, line 22. Rearward faces 264 are described on page 14, line 1 and a recessed head 232 is described beginning on page 13, line 27.

Therefore, Applicants respectfully request that the Examiner withdraw the objection to the drawings under 37 CFR 1.84(p)(5).

In the Specification:

The Examiner has objected to the specification for failing to provide proper antecedent basis for a safety retainer. As discussed above, Applicants have withdrawn claims 10, 19, 39 and 42 directed to a safety retainer.

As discussed above, Applicants have amended the specification to correct minor typographical errors and to more particularly describe the insertion needle 212 with forward end 212A.

In the Claims:

In this paper, Applicants have amended claims 1-4, 6-9, 11-16, 18, 20-28, 31-33, 35-38, 40, 41, and 43-46.

Applicants have added new claims 47 and 48. No new matter has been added. Support for the newly added claims may be found throughout the specification and in the figures.

I. Rejections under 35 USC §112

The Examiner rejected claims 1-16, 18-36, 38-43 and 45 under 35 USC §112, second paragraph. According to the Examiner, the reference numerals render the claims confusing.

Applicants have amended the claims to remove the reference numerals from the claims.

Accordingly, Applicants respectfully request that the Examiner withdraw the §112 rejections.

II. Claim rejections under 35 USC §102(e)

The Examiner rejected claims 1-12, 16, and 18-22 and 41 under 35 USC §102(e) as being anticipated by Safabash et al. (US 6,293,925). The Examiner maintains the rejection over Safabash and refers to FIG. 7 of the Safabash reference for meeting the claimed invention.

Applicants respectfully traverse the Examiner's rejection based on Safabash. Applicants respectfully request reconsideration of the rejected claims in light of the claim amendments and the traversals discussed below.

Safabash discloses an injector or insertion device 10 for inserting an insertion needle 12 of an insertion set 14 through the skin 16 of a patient. (Col. 8, lines 17-28.) The injector includes a plunger that moves between a rearward retracted position and a forward advanced position. When the plunger is in the advanced position as shown in FIG. 7, the needle 12 is removable from the plunger with minimum separation force.

As described in the specification, referring to FIG. 7, "When the plunger 30 reaches the fully advanced position, the safety lock arms 94 including their respective

pivot pins 98 are disposed within the wide cut outs 40 and are therefore free to swing outwardly, relative to the insertion set 14, to accommodate separation of the insertion set from the injector 10 with a substantially minimum separation force." (Col. 11, lines 43-49.) FIG. 7 illustrates the movement outward of the arms 94 for release of the needle 12 using arrows and the arms 94 shown in phantom no longer retaining the hub 18 of the needle 12 on the plunger. The safety lock arms 94 prevent accidental projection of the insertion set 14 through free space, in the event that the trigger button 38 is prematurely depressed. When the insertion set 14 is properly placed, however, the safety lock arms 94 release from the insertion set with minimal force, for easy separation of the injector 10 from the insertion set 14. (Col. 12, lines 5-11.) An alternative embodiment shown in FIGS. 17-29, the alternative safety lock mechanism again permits quick and easy separation of the injector 110 from the insertion set 14 with minimal separation force. (Col. 13, lines 14-16.)

Safabash teaches a needle that is clearly **removable** from the plunger. Safabash describes arms to prevent accidental projection of the needle indicating that the needle is removable. In addition, Safabash teaches arms that allow for easy separation of the needle of the insertion set from the plunger when the plunger is in the advanced position using substantially minimum separation force to achieve removal of the needle.

In contrast, Applicants' claimed invention for an injector device for placing a subcutaneous infusion set comprises a plunger having an insertion needle that is substantially non-detatchably secured to the plunger. The insertion needle remains connected to the plunger in the retracted and advanced positions. The insertion needle remains substantially non-detachably secured to the plunger when the cannula is removed from the insertion needle and the cannula maintains transcutaneous placement. The plunger has a generally cylindrical form with a head and a central pin including a metal insertion needle secured thereto in a molding process, by press-fit, or by any other method providing a suitable resistance to loss of the insertion needle during use of the device. (Page 10, lines 19-22). As described in the specification, by "substantially non-detachably" as used in the present application is meant a connection,

which will remain stable under normal conditions of use to allow the needle to remain on the plunger when retracting the injector device from a patient's skin. (Page 3, lines 10-13.) As shown in FIG.11, the needle remains substantially non-detachably secured to the plunger after insertion of the cannula into the skin and removal of the needle therefrom.

The needle of Applicants' invention remains substantially non-detachably secured to the plunger and cannot be removed with minimal separation force. Each of the independent claims 1 and 18 recites the requirement for the plunger having an insertion needle substantially non-detachably secured thereto by a connection such that the insertion needle remains connected to the plunger when removing the infusion set therefrom. New claims 47 and 48 recited that the insertion needle is substantially non-detachably secured to the plunger in the retracted position and the advanced position. The injector device claimed by Applicants, having an insertion needle substantially non-detachably secured to the plunger, is not taught by Safabash which teaches a releasable insertion needle that is removable from the plunger with minimal separation force.

Thus, Applicants assert that the claimed invention is not anticipated by Safabash. Applicants respectfully request the rejection of claims 1-12, 16, and 18-22 and 41 under 35 USC §102(e) be withdrawn.

Allowable Subject Matter

Applicants gratefully acknowledge the Examiner would allow claims 13-15 and 23-36, 38-40, 42, 43, 45 and 46 if amended to overcome the rejection under 35 USC §112, second paragraph.

Applicants have amended claims 13-15 and 23-36, 38-40, 42, 43, 45 and 46 to remove the reference numerals.

Applicants assert that the newly amended claims 13-15 and 23-36, 38-40, 42, 43, 45 and 46 are in condition for allowance. Early notification to such effect is earnestly solicited.

SUMMARY

Pending claims 1-9, 11-18, 20-38, 40, 41 and 43-46 as amended are patentable. Newly added claims 47 and 48 are also in condition for allowance. Applicants respectfully request the Examiner grant allowance of this application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

Heidi A. Dare
Registration No. 50,775
Attorney for Applicant

BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
CHICAGO, ILLINOIS 60610
(312) 321-4200

APPENDIX